REMARKS

Claims 1-8, 10, 15-16, 18-21, and 25 have previously been cancelled to expedite prosecution. Claim 17 stands withdrawn from consideration as being directed to non-elected species.

In order to emphasize the patentable distinctions of applicants' contribution to the art, claims 14, 22, and 26 (and claims 9, 11-13, and 24 respectively dependent thereon), have been amended to recite a marker comprising strips of magnetostrictive alloy that have an aspect ratio of at least about 4:1.

New dependent claims 27-29 are presented herewith to provide adequate coverage for applicants' contribution to the art. In particular, new claims 27-29 all require the aspect ratio of the magnetomechanically resonant strips to be at least 8:1, thereby restricting claims 12, 13, and 22, on which claims 27-29 respectively depend.

Support for the foregoing claim amendments and newly presented claims is provided by the specification; particularly at page 17, lines 15-18.

Applicants' invention, as delineated by remaining claims 9, 11-14, 22, 24, and 26, as amended, together with newly presented claims 27-29, is directed to a surgical implement detection system for detecting surgical implements within a wound at the conclusion of a surgical procedure. Compared to previously-known markers for article detection systems, the present inventive marker has a significantly reduced size. As a result, the marker is readily attached or similarly associated with surgical implements, including both reusable surgical tools, disposable items such as surgical sponges, or other like articles. The marker has a plurality of magnetostrictive amorphous metal strips disposed in a cavity with their orientation being non-parallel. The multiple directions greatly enhance the sensitivity of the marker to interrogating fields having different

directions, thereby markedly increasing, if not assuring, the detection of the marker and a surgical implement associated therewith while the implement is still located within a patient's body during surgery. The marker's smaller size permits it to be attached to items that otherwise could not be protected. In some cases, a surgical item is simply too small to accommodate a conventional marker. The item may be smaller than the typical 1.5" length of a marker operative at about 60 kHz, or it may have no suitable location large enough for such a marker to be placed on it. The marker employs magnetomechanically resonant strips having an aspect ratio of at least about 4:1, and in some preferred implementations, at least about 8:1. This high aspect ratio advantageously limits the width of the resonant strips, thereby permitting the housing enclosing them to be correspondingly narrower. In other instances, a conventional marker accompanying an item or attached to it would be an impediment to the item's ordinary use, e.g. by interfering with a surgeon's manipulation of the item. Applicants maintain that the prior art has failed to recognize the potential for a smaller, more widely applicable marker that could avoid these detriments.

The problem of implements left behind after the completion of surgical procedures remains a serious and vexing medical issue, because if undetected, these items are highly likely to cause serious, and possibly fatal, injury to a patient. The present system provides a procedure whereby these items can be reliably, quickly, and efficiently detected in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required.

Claims 9, 11-14, 22, 24, and 26 stand rejected under 35 USC 103(a) as obvious over US Patent No. 5,057,095 to Fabian, in view of US Patent No. 5,338,373 to Von Hoene et al., US Patent Publication 2002/0005738 to Irizzary et al., US Patent 6,359,563, US Patent 6,407,676 to Tanji et al., and US Patent 4,510,490 to Anderson, III, et al.

Fabian discloses a surgical implement detector utilizing a resonant marker. In one embodiment, the Fabian marker is magnetomechanical.

Von Hoene et al. provides a process for making a large number of magneto-mechanically resonant markers having distinct resonant characteristics.

Irizzary et al. provides a system and method for monitoring the departure of a child from a retail store or other area wherein a magnetomechanical electronic article surveillance system has previously been installed.

Tanji et al. provides a magnetostrictive resonator appointed to be embedded in a roadway for use in connection with a vehicle detection system.

Anderson, III, et al. provides a surveillance system having a coded magnetomechanical marker.

With respect to claims 12-14, 22, and 26, the Examiner has stated that Fabian teaches a system for detecting surgical implements using a magnetomechanical marker having a resonant frequency, which applicants acknowledge. The Examiner further indicated that the Fabian system provides three types of resonance, magnetomechanical, electromechanical, and electromagnetic. It is important to recognize that Fabian's disclosure an overall upper bound of 1 GHz for the resonant frequency is made only in the general context of all systems of all three types. However, there is no disclosure or suggestion that systems embodying each of the three types of resonance (magnetomechanical, electromechanical, and electromagnetic) may be constructed to

operate at frequencies approaching 1 GHz. The Examiner has taken cognizance of applicants' citation of col. 8, lines 9-10 of Fabian as being the only guidance provided as to the operating frequency of a magnetomechanical system, namely that the frequency be one "used by a conventional system."

The Examiner has acknowledged that Fabian fails to teach a specific range of frequencies or a plurality of magnetostrictive strips disposed in a cavity in non-parallel orientation, as recited by base claims 14, 22, and 26 and claims 9, 11-13, and 24 variously dependent thereon.

Accordingly, he has pointed further to Von Hoene et al. as allegedly motivating the skilled person to employ strips of different lengths to allow different articles to be detected. He has specifically pointed to an example of a resonant strip having a length of 1.8 cm and a resonant frequency of 120.21 kHz.

As set forth at page 8, line 19 to page 9, line 3; page 18, lines 1-15; and page 18, line 23 to page 19, line 10, a marker constructed to operate within applicants' claimed frequency range advantageously is smaller in size than conventional magnetomechanical markers used in connection with a surgical implement, such as that disclosed by Fabian, but nevertheless has an adequate volume of magnetic material to emit a signal that is large enough to permit highly reliable, rapid detection of the marker in the adverse environment of surgery.

Even less does Von Hoene et al. recognize the need to employ resonant strips having an aspect ratio that is adequately high (e.g., a ratio of at least about 4:1) to assure a well-defined resonance, e.g. as taught by applicants at page 17, lines 12-15 of the specification. By way of contrast, Table I of Von Hoene et al. discloses magnetomechanical strips that have lengths ranging from 1.8 to 6.4 cm, corresponding to resonant frequencies between 120.21 and 33.28 kHz. However, all these strips were 1.27

cm wide (See col. 8, line 42). Notwithstanding the shortening of the strips to increase the resonant frequency, a constant width was maintained for all the examples of Table I. Even at the lowest frequency of 33.28 kHz, the strip had an aspect ratio of just 5:1. For a 1.27 cm wide strip, an aspect ratio of 4:1 corresponds to a length of 5.08 cm, for which the resonant frequency would be about 42.4 kHz by interpolation. The 3.15 cm Von Hoene strip with a resonant frequency of 69.61 kHz has an aspect ratio of about 2.5:1, and the aspect ratio drops to 1.4. Significantly, Von Hoene states only that "the physical length of the alloy strip must be greater than the width" (col. 4, lines 5-6) and that "the width and thickness of the alloy strip are also not critical, and are dictated primarily by the casting conditions" (col. 4, lines 12-14). None of the Von Hoene strips even approaches the preferred aspect ratio of 8:1 recited by claims 27-29.

Therefore, there is nothing in Fabian, even in light of VonHoene et al., to suggest the reconstruction required by the Examiner's proposal. Clearly, speed and reliability of detection are of paramount importance in such a situation. On the other hand, increasing the operating frequency of the detection system necessarily decreases the length of the resonant element of the marker. In addition, the reducing the length also typically necessitates decreasing the width of the element in order to maintain a comparable demagnetizing factor. The decrease in total element volume in turn inherently reduces the signal output the marker provides. The prior art has thus eschewed shorter, higher frequency markers, regarding them as providing inadequate output to permit reliable marker detection. On the other hand, applicants' marker is capable of providing sufficient output as a result of the particular configuration taught. Advantageously, the compact size of the present marker permits surgical items to be tagged that would be physically impossible to tag using larger conventional markers. As set forth above, many surgical items either do not have a suitable location on which to situate a conventional marker, or

the use of the item would be adversely impacted by the presence of the marker. On the other hand, the smaller markers provided by applicants can be used beneficially in such situations. The non-parallel orientation of the strips in the marker further enhance the probability that the marker will, in fact, be detected during its appointed use during surgery.

Applicants respectfully submit that Von Hoene et al. fails to disclose or suggest any marker configuration that involves a magnetostrictive element having multiple, non-parallel resonant strips of amorphous metal. Accordingly, Von Hoene et al. does not cure the deficiency of Fabian.

Furthermore, the Von Hoene et al. reference is directed to a method of encoding and decoding a glassy alloy strip to be used as an identification marker. Attention is further drawn to the disclosure at col. 4, lines 18-24, in which the patentees state that "The fundamental aspect of this invention is that the modification to the alloy strip be of such a nature as to change the effective length of the marker. The effective length of an alloy strip may be calculated for a modified strip by using the physical length and resonant frequency of an unmodified strip having the same composition."

While Von Hoene et al. admittedly discloses in Table I a magnetomechanically resonant strip having a resonant frequency of 120.21 kHz, it is submitted that such disclosure falls short of rendering obvious the use of such a strip in a marker appointed for an EAS system, let alone a marker attached to a surgical instrument so as to render such instrument detectable in the manner provided by applicants' invention. The object of the Von Hoene et al. invention, to the contrary, is to provide a large plurality of unique and measurably discernable markers (see, e.g., col. 2, lines 46-59), wherein the resonant frequency is determined by the effective length of a marker element, not the actual length. Nothing in Von Hoene et al. contemplates or suggests the use of any marker having a

120.21 kHz resonant frequency, let alone such a marker in a medical or surgical context. To the contrary, the various techniques for modifying the effective length of marker disclosed by Von Hoene et al. were all implemented using markers having a resonant frequency of about 55-69 kHz, as provided in Examples 2-7. The Examiner has suggested that Von Hoene et al. teaches changing the length of the marker. However, he has relied on a passage that relates to changes in effective length resulting from particular processing and not from changes in the actual length of the marker element.

By way of contrast, the present invention provides a marker attachable to a surgical instrument, the marker being of significantly reduced size compared to conventional markers operating at lower frequency. As a result, the marker enables the reliable, quick, and efficient detection of retained instruments in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required. The small size further permits instruments to be tagged that could not be tagged with larger prior art markers. None of these beneficial attributes is afforded by any marker or tagged instrument constructed in accordance with the teachings of Fabian and Von Hoene et al., even if taken in combination.

It is thus respectfully submitted that even in combination, Fabian and Von Hoene et al. do not disclose or suggest the method of claim 14, the surgical implement of claim 22, or the system delineated by claim 26, as amended, let alone the features of claims 9, 11-13, 24, or 27-29 dependent thereon.

The Examiner has further cited Irizarry et al., Herzer, Anderson, and Tanji. Applicants respectfully submit that none of these references, even if combined with the Fabian and Von Hoene references, overcomes the latter references' failure to disclose or

suggest the use of a marker having the required resonant frequency and the aspect ratio of the magnetomechanical strips employed therein.

The Examiner alleges that Irizarry et al. teaches a magnetomechanical maker employing two non-parallel strips to increase the detection rate of the marker and that it would have been obvious to include "the concept of non-parallel strips as taught by Irizarry et al. with the marker taught by the combination of Fabian and VonHoene et al. to provide the benefit of increasing the detection rate of the marker, as taught in paragraph [0034] of Irizzary et al."

Significantly, the embodiment of Irizarry to which the Examiner likely refers, i.e. that depicted by Irizzary's Fig. 2, is said to be a tag that includes two magnetomechanical markers. *See* paragraph [0025]. Irizzary et al. indicates that the improved detection is afforded by provision of multiple markers oriented in different directions. Each marker includes a distinct magnetomechanical element and a distinct bias element. *See* paragraphs [0034] and [0036]. Clearly, Irizzary et al. does not contemplate a structure in which a single marker employs plural, non-parallel magnetomechanical elements housed in a single cavity.

More specifically, applicants respectfully submit that the tag of Irrizary et al. comprises two magnetomechanical markers, having elongated axes that are perpendicular. Whereas each of the mechanical markers (e.g. markers 25 and 26 of tag 21 shown in Fig. 2) of Irrizary et al. separately includes a magnetomechanical elongated strip, applicant's marker includes a magnetomechanical element comprising a plurality of elongated strips. Present claim 26 recites in feature (a)(iii) a housing having a cavity enclosing the magnetomechanical element (a plurality of elongated strips, from feature (a)(i)) disposed in the cavity in a non-parallel orientation with their centers coincident. Therefore, it is respectfully submitted Irrizary et al. does not disclose a marker wherein a

magnetomechanical element comprises plural strips that collectively constitute a magnetomechanical element and are together enclosed in a cavity of a housing. Rather, the Irrizary et al. marker comprises multiple magnetomechanical elements that are enclosed in cavities in separate housings, even if the multiple markers are mechanically joined. Irizzary et al. further fails to disclose or suggest the particular resonant frequency range delineated by applicants, thereby failing to cure the aforementioned deficiency, even if all the applied references are taken in combination.

The Examiner has further argued that Herzer, Tanji, and Anderson disclose markers in which multiple magnetostrictive strips are present in a single cavity. Applicants do not dispute this general proposition, but respectfully observe that in each of these references, the markers disclosed use strips disposed in a parallel orientation. No non-parallel orientation is disclosed or suggested.

The Examiner has purported that it would have been obvious to one having ordinary skill to place the multiple strips of the combination of Fabian, Von Hoene, and Irizarry in a single cavity in a single housing in place of two separate housings for gaining one or all of the advantages set forth by Herzer, Tanji, and Anderson.

Applicants respectfully submit that the foregoing statement of motivation to combine the references in the manner proposed is at best conclusory, and far short of the legal standards for an obviousness rejection set forth by the Supreme Court in *KSR v. Teleflex*, 127 S. Ct. 1727; 2007 U.S. LEXIS 4745; 75 U.S.L.W. 4289 (2007). In particular, the court held that there must be an explicit analysis to establish the factual determinations needed for the traditional test for obviousness required under *Graham v. John Deere Co.*, 383 U.S. 1, 14, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545, 148 USPQ 459, 465, 467 (1966). See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1435 (Fed. Cir. 2002) (finding that reliance on "common knowledge and common sense" did not fulfill the PTO's obligation

to cite references to support its conclusions as PTO must document its reasonings on the record to allow accountability and effective appellate review).

More specifically, reference to "one or all of the advantages" neither identifies such purported advantages nor establishes their pertinence to the present subject matter. In order to be able to respond, applicants would be forced to identify a multiplicity of auch "advantages" and respond to every possible permutation thereof. It is respectfully submitted that the Examiner has no legal warrant under MPEP 706.02(j) and 37 CFR 1.102(c) for omitting the required analysis and transferring any part of this obligation to applicants.

Furthermore, some of the advantages set forth in one or more of the cited references would negate at least some of the advantages of applicants' non-parallel orientation. For example, Herzer alleges improved marker response by provision of multiple magnetomechanical strips in parallel orientation. That advantage would be negated with non-parallel orientation, because of the known orientation-dependence of signal response, and so cannot furnish the motivation alleged by the Examiner for using multiple strips. While the parallel strip orientation of a Herzer marker may provide some improvement in the detectability of a Herzer marker that is favorably oriented with respect to a detection apparatus, it does not provide any solution to the problem recognized by Irrizary et al. of response by unfavorably oriented markers. *See* lines 9-15 of paragraph [0034] of Irrizary et al. Only in light of applicants' own teaching is there recognition that non-parallel strips, housed in a single cavity, provides improved orientation detectability without necessitating the impermissible operation of hindsight and the far more difficult and complex construction required by the Irrizary et al. multiple-marker construction.

With respect to applicants' purported failure to address the teachings of the Tanji et al. reference in the response dated November 21, 2007 to the Office Action dated August

21, 2007 (see the instant Office Action at page 7, last three lines), it is respectfully observed that the August 21 Office Action did not include any statement rejecting any pending claim over the Tanji et al. reference. Accordingly, applicants are not aware of any legal requirement to address said reference.

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., Herzer, Irrizary et al., Tanji et al., and Anderson, III, et al. do not disclose or suggest the system delineated by applicants' claims 14, 22, and 26. Applicants maintain that claims 9, 11-13, and 27-28 dependent from claim 26 and claims 24 and 29 dependent from claim 22 are patentable for at least the same reasons as their respective base claims.

Accordingly, reconsideration of the rejection of claims 9, 11-14, 22, 24, and 26 under 35 USC 103(a) as being unpatentable over Fabian and VonHoene et al., whether with or without the further addition of Herzer, Irrizary et al., Tanji et al., and Anderson, III, et al. is respectfully requested.

CONCLUSION

In view of the amendment of claims 14, 22, and 26, and foregoing remarks, it is respectfully submitted that the present application has been placed in allowable condition. Reconsideration of the rejection of claims 9, 11-14, 22, 24, and 26 and allowance of the present application, as delineated by amended claims 9, 11-14, 22, 24, and 26, together with newly presented claims 27-29 are, therefore, earnestly solicited.

Respectfully submitted,

Carl E. Fabian, et al.

Ernest D. Buff

By

Ernest D. Buff
(Their Attorney)
Reg. No. 25,833
(908) 901-0220